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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,514	11/17/1998	MIE KAINOH	1102-98	8751

7590

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EXAMINER

SCHWADRON, RONALD B

ART UNIT

PAPER NUMBER

1644

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/155,514

Applicant(s)
Kainoh et al.

Examiner
Ron Schwadron, Ph.D.

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-9 and 25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-9 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/17/2002 has been entered.

2. Claims 2-9,25 are under consideration. Claims 24,45-49 have been canceled. Claims 2,3,5,25 have been amended.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-9,25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent 5,821,333) in view of Hori et al. (US Patent 5,916,771) and prior art disclosed in the specification (see references disclosed in pages 2 and 3 of specification) for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule (see columns 19 and 20). Carter et al. teach that said molecules are bispecific immuno adhesions (see column 19). Said molecules need to have two functioning chains in order to function as a bispecific immuno adhesion. Carter et al. teach that such molecules can be dimers, wherein the two chains contain different adhesion molecules wherein the two adhesion molecules are both fused to heavy chain Ig constant regions (see column 19, last paragraph, continued on next page). Carter et al. do not specifically teach that the adhesion molecules are derived from an α and β chain of an integrin. Hori et al. teach that β_1 integrin molecules were known in the art as heterodimeric molecules (see column 5). The prior art disclosed in the specification, pages 2 and 3 indicates that all of the integrin chains recited in the claims were known in the art. The prior disclosed in the specification, page 3 indicates that

β_1 integrin molecule was known in the art as heterodimeric molecule containing a β_1 and an α_4 chain Carter et al. teach that Ig fusion proteins have a variety of art recognized uses (see column 4). Hori et al. teach recombinantly produced dimeric integrin molecules (see column 5). Carter et al. also teach recombinantly produced dimeric adhesion molecules (see columns 19 and 20). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule while Hori et al. teach that β_1 integrin molecules were known in the art as heterodimeric molecules and that such molecules can be recombinantly produced. One of ordinary skill in the art would have been motivated to do the aforementioned because Carter et al. teach that Ig fusion proteins have a variety of art recognized uses (see column 4). Carter et al. teach use of Ig fusion proteins as drugs (see column 4). The various integrin molecules recited in the claims were all known in the art. Human Ig heavy chain sequences are known in the art (see Carter et al., columns 18 and 19).

Regarding applicants comments about the specification page 7, Carter et al. is an issued US Patent which contains claims drawn to recombinantly produced heteromultimeric peptides. The claims of an issued US Patent are considered valid and enabled. The claimed invention is a recombinantly produced heteromultimeric peptide. Furthermore, the specification page 7 refers to prior art specifically disclosed in the specification, but does not address the prior art cited in the instant rejection. Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule (see columns 19 and 20). Carter et al. teach that such molecules can be dimers, wherein the two chains contain different adhesion molecules wherein the two adhesion molecules are both fused to heavy chain Ig constant regions (see column 19, last paragraph, continued on next page). Carter et al. teach that immunoadhesions have a variety of art recognized uses (see column 4, third paragraph). Integrins are art known adhesion molecules. All of the integrin chains recited in the claims were known in the art. Carter et al. teach that immunoadhesins have a variety of art recognized uses for therapeutic and diagnostic purposes (see column 4, third paragraph). One of ordinary skill in the art would have been motivated to do have created the claimed invention in view of the cited references because Carter et al. teach that adhesion molecule/Ig fusion proteins have a variety of art recognized uses and integrins are adhesion molecules. Regarding applicants comments about motivation, integrins are an art known form of adhesion molecule. Immunoadhesion molecules

have a variety of art known uses (see columns 34-36 of Carter et al.). Regarding applicants comments about use of the instant invention as a platelet substitute, none of the claims under consideration are drawn to a platelet substitute. Furthermore, there is actually no in vivo data demonstrating that the claimed invention could be used in vivo as a platelet substitute.

4. No claim is allowed.

5. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are

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unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.

Primary Examiner

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RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1600 | 600